

12D



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,260	06/19/2001	Alan Brash	06027.0002U2	3583
23859	7590	08/06/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C.			NASHED, NASHAAT T	
SUITE 1000				
999 PEACHTREE STREET			ART UNIT	PAPER NUMBER
ATLANTA, GA 30309-3915			1652	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/884,260

Applicant(s)

BRASH ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/14/01.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1652

The application has been amended as requested in the communication filed June 17, 2004. Accordingly, claims 20 and 21 have been amended and new claims 22-31 have been entered.

The election of Group IVb with traverse in the response to the second restriction requirement mailed May 14, 2004 is noted. Applicants' arguments traversing the restriction requirement of Groups IVa-IVe are found persuasive, and therefore, the restriction between Groups IVa-IVe has been vacated.

Claims 20-31 are under consideration in this Office action.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, Figures 1A-1G contain several amino acid sequences, which are not identified by a sequence identification number in the Figure or its description. Claims 25 and 30 refer to a specific polypeptide sequence disclosed in the specification without identifying the sequence with a sequence identification number. Applicants must perfect their compliance with sequence rule.

Claim 20 and 21 are objected to under 37 CFR 1.75(d)(1) as being in improper form because the claim states an improper Markush groups. Compounds included within a Markush group must: (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. (See MPEP, 803.02.). The various members of the Markush group in the claims are different chemical compound and do not share a common structural feature required for the stated utility. Each of claims 20 and 21 should be split into two independent method claims, each of which contains one substrate for hydroperoxide lyase.

Claims 20 and 21 are objected to because of the following informalities: The steps in the methods claims are not designated by sequential alphabetic order. Step (b') should be step (c), and step (b'') should be step (d). Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

Art Unit: 1652

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20-24 and 27-29 are directed to methods of making aldehydes using a hydroperoxide lyase and a hydroperoxide of long chain fatty acids, wherein said hydroperoxide lyase is from any source as long as it can act on both 9-hydroxyperoxide and 13-hydroxyperoxide substrate and that the  $K_m$  and  $V_{max}$  for the 9-hydroperoxylinolenic acid are greater than those values for 9-hydroperoxylinoleic acid. The specification, however, only provides a single representative species from *Cucumis melo* or muskmelon (SEQ ID NO: 7) encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these hydroperoxide lyases by any identifying structural characteristics or properties other than the activities recited in claim 20 and 21, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 20-24, 26-29, and 30 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a method of making the compounds listed in claims 20 and 21 utilizing hydroperoxide lyase of SEQ ID NO: 7. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to all possible hydroperoxide lyases which act on both 9-hydroxyperoxide and 13-hydroxyperoxide substrate and that the  $K_m$  and  $V_{max}$  for the 9-hydroperoxylinolenic acid are greater than those values for 9-hydroperoxylinoleic acid. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any hydroperoxide lyase which acts on both 9-hydroxyperoxide and 13-hydroxyperoxide substrate and that the  $K_m$  and  $V_{max}$  for the 9-hydroperoxylinolenic acid are greater than

Art Unit: 1652

those values for 9-hydroperoxylinoleic acid from any biological or man-made source. Claims 26 and 31 further limit claims 20 and 21, respectively, to a lyase comprising the amino acid sequences of SEQ ID NO's: 1-6 which are fragments of SEQ ID NO: 7 ranging in length between 7-15 amino acid residues. The specification provides guidance and examples in the form of an assay to isolate the nucleic acid sequence of SEQ ID NO: 8 encoding the 481 amino acid sequence of SEQ ID NO: 7 (see examples). While molecular biological techniques and genetic manipulation to search for naturally occurring genes and constructs mutants thereof are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological source of such lyase with specific characteristics, methods of redesigning the protein of SEQ ID NO: 7 around 7-15 amino acids while maintaining the characteristics cited in the claims, the amino acid residues in SEQ ID NO: 7, which are required to impart the desired catalytic properties cited in the claims and those required for folding the polypeptide into functional protein, and the three dimensional structure of SEQ ID NO: 7 is lacking. Thus, searching for a hydroperoxide lyase with the cited characteristic is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a nucleic acid sequence encoding hydroperoxide lyase with the specific characteristics cited in claims 20 and 21 from a natural source, *de novo* constructing hydroperoxide lyase to include 7-15 amino acid residues of SEQ ID NO: 1-6 having specific characteristics, or obtaining insertion, deletion, substitution, and combination thereof mutants of SEQ ID NO: 7 with specific characteristics is enormous. Since routine experimentation in the art does not include screening vast numbers of gene libraries, cDNA libraries, and man-made DNA libraries where the expectation of obtaining the desired lyase is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the biological source of such enzyme, the structural feature required to maintain the substrate specificity and catalytic properties, the three dimensional structure of the protein of SEQ ID NO: 7. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Claims 20 and 21 are generally narrative and confusing, failing to conform to current U.S. practice.
- (b) Claims 25 and 30 is directed to a method utilizing a specific hydroperoxide lyase without identifying the lyase with a sequence

Art Unit: 1652

identification number which renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

(c) Claims 22-24, 26-29, and 31 are included with these rejections because they are dependent from a rejected claim and do not cure their deficiencies.

Allowable subject matter:

Claims directed to the embodiments of claims 25 and 30 would be allowable provided that said claims are free of rejections under 35 U. S. C. 112, second paragraph, and in compliance with the sequence rule.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1652